Development of Pharmacy Operating Procedures for the Implementation of Antiretroviral Therapy in Ethiopia
Trip Report

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

The visit was conducted to support the development of the pharmaceutical management system for antiretroviral drugs. During two review meetings main procedures for the management of antiretroviral drugs at facility level were agreed within the working group. Manual forms for information management were designed and features of an electronic information management system discussed.

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Contents

Acronyms

ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
CDC	U.S. Centers for Disease Control and Prevention
DACA	Drug Administration and Control Authority
EHNRI	Ethiopian Health and Nutrition Research Institute
ETAEP	Ethiopian AIDS Emergency Plan
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HAART	highly active antiretroviral therapy
HAPCO	HIV/AIDS Prevention and Control Office
HC	health center
IDA	International Dispensary Association
KENEMA	community-owned pharmacies
MIS	management information system
MOH	Ministry of Health
MSH	Management Sciences for Health
OI	opportunistic infection
PASS	Pharmacy Administration and Supply Service
PHARMID	Pharmaceuticals and Medical Supplies Import and Wholesale Share Company (parastatal import and distribution company)
PMTCT	prevention of mother-to-child transmission
RHB	Regional Health Bureau
RPM Plus	Rational Pharmaceutical Management Plus Program
SOP	standard operating procedures
TB	Tuberculosis
UNICEF	United Nations Children's Fund
VCT	voluntary counseling and testing
WHO	World Health Organization
woreda	district (in Amharic)

Background

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program, is collaborating with USAID Ethiopia in the provision of technical assistance in the area of drug and supplies management under the President's Mother and Child HIV Prevention Initiative and the President Emergency Plan for AIDS Relief.

Under this effort, RPM Plus assists in ensuring access to quality products for the Prevention of Mother to Child Transmission (PMTCT) and antiretroviral therapy (ART) services and their rational use by strengthening pharmaceutical management capacity at national, regional, district and health facility-level, including the up-grading of pharmacy and laboratory infrastructures and procurement of selected supplies necessary for service implementation and scale-up

Purpose of Trip

RPM Plus had carried out site assessment at 25 hospitals earmarked for the introduction of ART with United States Government support. ARV drugs are being procured for the start-up of services.

A working group representing DACA, PASS/MOH, HAPCO, KENEMA and RPM Plus has written Standard Operating Procedures (SOPs) for ARV drug management that is still in draft. RPM plus is also designing an access-based MIS system for ART patient and product tracking to be used at hospital pharmacies, ARV distribution and management units including PASS.

Hella Witt, Senior Program Associate for MSH/RPM Plus provide technical assistance in the review, refinement and introduction of the SOP and MIS tools at the selected sites.

Hella arrived in Addis Ababa on October 16, 2004 and departed November 23, 2004.

Scope of Work

1. Provide technical assistance in the review and finalization of the draft SOPs for the management of HIV- commodities
2. Assist in the introduction of the newly developed access-based data system and manual stock/patient tracking & reporting system in selected sites
3. As needed, assist in the planning of further steps for achieving site readiness for the introduction of ART
4. Present findings from the Pharmaceutical/Laboratory assessment of the fifteen hospitals and the TB-HIV collaboration in the area of pharmaceutical management
5. Brief USAID and partners on activities and next steps

Activities

1. Provide technical assistance in the review and finalization of the draft SOPs for the management of HIV- commodities

Standard operating procedures for the management of ARV drugs are important to assure that drugs procured with US Government funds are appropriately used at the health facilities. The program shall support the national implementation of free provisions of ART and a national approach in the development of standard operating procedures for ARV drug management at the facility level. DACA and the MOH are the main stakeholders to foster adoption of uniform procedures at the health facilities and drug dispensing outlets. DACA and MOH welcomed the idea and agreed to participate in the process. MSH and DACA took the responsibility to sponsor the development of a draft SOP. A working group with members from RPM Plus (MSH), DACA, PASS (MOH) and KENEMA Pharmacies (Public drug retail outlets currently dispensing ARVs) was formed that had met for 10-days to develop the first draft SOP for ARV drug management at facility level.

Hella Witt reviewed the draft SOP. The comprehensive document defined roles and responsibilities of pharmacy staff; and described procedures for ordering, receiving, storage, exchange, disposal and distribution of ARVs at heath facilities. The procedures for medication use counseling, reporting, and internal audits were also included. In view of the development of an efficient MIS the inclusion of additional management tools and the improvement of recording and reporting forms were recommended. Most changes were necessary to ease ARV quantification at the facility level monitoring ARV drug consumption and use, and to simplify monitoring and reporting. Findings of the technical revision were first discussed with Hailu Tadeg, Pharmaceutical Management Advisor MSH/RPM Plus Ethiopia. Modified forms and procedures were prepared for discussion within the SOP working group. Two consecutive SOP working group meetings were held at the MSH office on October 29 and November 17, 2004.

The first review meeting was attended by Getahun Gurmessa (DACA), Sileshi Birhanu (PASS/MOH), Ayalew Adinew (KENEMA) Hailu Tadeg, Shimelis Endailalu and Hella Witt (MSH). During a full day meeting, major changes were discussed and agreed to, see Annex 1 for minutes of the meeting.

Based on the agreements of the first review meeting, the drug management tools were refined. Together with MSH consultant Hare Ram different aspects of the patient information and of the drug register were discussed in view of the further development of an electronic management system at facility level. Procedures for internal auditing were recommended to be simplified to limit the work load of monitoring team.

At the second SOP review meeting on November 17, 2004, the emphasis was on the finalization of the major ARV drug management tools and reporting forms which had been further improved by MSH staff. Also the simplified monitoring procedures were discussed and agreed between the partners. MSH was assigned to finalize the monitoring forms according to the agreed framework and to incorporate the changes agreed during the meetings into the draft SOP. After the second review meeting the participants agreed upon the main ARV management procedures and tools,

which were considered final working drafts to be presented to DACA and MOH senior staff for final approval.

Facility ARV drug quantification

The procedures identified in the revised SOP for the data required for ARV quantification will be available to the pharmacist. The procedures and forms are designed for the pharmacist to make an informed judgment on the number of patients expected to be treated in the next month. Communication with prescribers is required to anticipate changes in patient intake and prescribing behavior.

Hella Witt drafted forms and procedures recommended for facility ARV quantification. The recommended quantification process is based on the following principles and main assumptions:

- Simplicity, as the facilities themselves need to be able to regularly carry out quantification with little effort
- No significant gender difference are applied as men and women receive the same first-line regimen according to Ethiopian guidelines
- The majority of patients will receive the first-line treatment recommended by the ART guideline development group
- Significant transfer of patients between ARV dispensaries is possible
- Most facilities will order on monthly basis, but some may maintain longer order cycles

The quantification process was discussed with Hare Ram Bhattarai and Hailu Tadeg and the omission of one quantification step was recommended to further simplify the process.

2. Assist in the introduction of the newly developed access-based data system and manual stock/patient tracking & reporting system at selected sites

Hare Ram Bhattarai had designed an electronic data base for the management of ARV drugs at the facility level. A manual stock/patient tracking & reporting system was developed during the SOP development process. The procedures and forms designed for the manual system made it necessary to introduce a few changes in the electronic system. Hare Ram, Hella and Hailu discussed various aspects of the design of the electronic data base, which Hare Ram will develop accordingly.

Forms for information management between health facilities, PHARMID and the MSH office were also designed. The forms were discussed with the PHARMID General and Procurement Manager. It was confirmed that the PHARMID branches and head office can regularly report the required data on drug distribution and stock status.

Hare Ram, Hella and Hailu also discussed the design of an Access-based MIS system for ARV drugs which could be used at regional and central level.

3. Assist in the planning of further steps for achieving site readiness for the introduction of ART

MSH has carried out different assessments to investigate the pharmacy management capacity at health facilities earmarked for the introduction of PMTCT and ART with US Government support. The Ethiopian health authorities had however not conclusively defined which facilities should be supported by ETAEP and the Global Fund. In the meantime national ART implementation guidelines had been drafted, which outline a minimum package of clinical, pharmacy and laboratory requirements for the implementation of ART at a facility. Recent MSH assessments were orientated towards this minimum package.

The pharmacy minimum package for ART implementation defines requirements for pharmacy infrastructure, equipment and supplies, human resources, M&E/MIS. In order to translate the minimum requirements into tangible facility indicators, Hella Witt and MSH Ethiopia technical staff discussed the indicators that should consistently be applied at health facilities intending to dispense ARV with support from ETAEP. All indicators are strictly oriented towards the minimum package and are intended to present the minimum requirements for the start-up of services while ongoing support will be required to increase efficiency of pharmaceutical services during the scaling-up period. While the pharmacy indicators were shared with CDC and I-Tech, attempts to contact the head of PASS (MOH) were not successful.

The availability of standard operating procedures for ARV drug management and a Memorandum of Understanding with the facilities are among the minimum indicators defined by MSH for pharmacy site readiness (Annex 2). Hella Witt drafted a MOU to define responsibilities for ARV drug management at health facilities supported by ETAEP. The draft will be discussed and refined by MSH Ethiopia.

Dr Negussu Mekonnen participated in a recent meeting where the MOH and DACA identified the sites which shall be supported by ETAEP. This agreement significantly increases MSH ability to plan for pharmacy site preparedness and to arrange for respective ARV drug distribution.

4. Present findings from the Pharmaceutical/Laboratory assessment of the fifteen hospitals and the TB-HIV collaboration in the area of pharmaceutical management

The findings of the Laboratory assessment were discussed with Dr Yohannis Mengistu of the CDC. During the meeting Hella Witt also introduced the list of pharmacy preparedness indicators resulting from the pharmacy assessments. A similar approach was integrated in the laboratory assessment report, but the indicators were less specific as it was anticipated that CDC was going to define the laboratory indicators for the facilities.

In a meeting with the TB program manager, program pharmacist and TB/HIV coordinator, the MSH assessment findings for TB-HIV collaboration in Ethiopia were discussed. The TB/HIV coordinator briefed Hella about recent developments and provided her with latest up-dates of the

country proposal for TB/HIV collaboration and drafted guidelines for preventive therapies. The MOH requested the collaborative initiatives move from the pilot stage to broader implementation and the 50 ART implementation sites anticipated to be targeted for such collaborative activities. As MSH was working on the development of the pharmacy operating procedures, there was an opportunity to reflect on the approach in the facility documentation. Questions regarding preventive and TB treatment were included into the information regularly recorded by the pharmacies. In a second meeting Hella informed the TB/HIV coordinator and pharmacist about the planned integration of the information. She highlighted that the inclusions into the facility documentation would only capture information from patients on ART and not other HIV-infected patients not yet requiring antiretroviral treatment. Upon a first review of the documents provided to MSH, other pharmaceutical management issues of common concern were discussed. According to the draft proposal for TB/HIV collaboration, the TB/HIV program will be responsible for the supply management which will include HIV test kits. The order of these commodities will go through PASS. As the collaborating activities are still in an early stage of proposal development, no management system has yet been developed for the supplies provided through the TB/HIV collaborative approach. The TB/HIV coordinator requested further comments and inputs from MSH.

5. Brief USAID and partners on activities and next steps

Hella Witt met with Dr Ohmar Ahmed at USAID during the first week of the visit give a brief description of the planned activities.

Hella Witt met with CDC to discuss the laboratory assessment and preparedness. Dr Yohannis Mengistu indicated that the distribution of laboratory supplies needs to be managed and may approach USAID/MSH for discussion on this issue.

Monitoring PMTCT supplies

The United Statues Government is supporting the provision of PMTCT at 23 hospitals and health centers through the Hareg project. The support is planned to be expanded to another 22 health centers. In order to facilitate monitoring of supplies provided to the sites, MSH technical staff designed monitoring forms.

PMTCT supplies are procured by UNICEF and received from the AXIOS donation program. Some supplies are intended for structural support for PMTCT provision (e.g. refrigerators), others are regular consumables at the facilities (e.g. gloves) and some items are core for PMTCT (e.g. nevirapine). To account for the different nature of the products and respective monitoring requirements two monitoring forms were developed.

PMTCT core supplies need intensive monitoring at the user level (ANC, laboratory, Maternity ward). The forms developed for monitoring the consumption of these items tie in with regular reporting requirements of the MOH, in particular monthly summary reports for PMTCT and reporting of VCT activities. For other PMTCT consumables that are used for different services and that don't need to be monitored as closely, monitoring shall be limited to the health facility main store. Both forms are designed to provide facilities with the information required to order

appropriate quantities of supplies from the Hareg project and other sources. The use and regular up-dating of stock records is necessary for the facility to report on the consumption and stock status of the commodities.

Collaborators and Partners

MSH Ethiopia	Dr. Negussu Mekonnen, Senior Program Associate Haile Wubneh, Senior Program Associate Hailu Tadeg, Pharmaceutical Managment Advisor Shimelis Endailalu, Pharmaceutical Managment Advisor Frehiwot Tadesse, Pharmaceutical Managment Advisor
MSH US	Gabriel Daniel, Senior Program Associate Hare Ram Bhattarai, Senior Program Associate
DACA	Getahun Gurmessa
PHARMID	Girma Bedasso, General Manger Yemanebirhane Tadesse, Procurement Manager Sintayehu Belachew, Clearing Officer
CDC	Dr. Yohannes Mengistu
MOH	Sileshi Birhanu, PASS Tesfaye Abicho,TB/HIV Coordinator Zerihun Tadesse, TB and Leprosy Program Manger Amare Moges, Pharmacist of the TB program
I-TECH	Tesfai Gegre-Kidan Misrak Makonnen

Adjustments to Planned Activities and/or Additional Activities

Not applicable

Next Steps

Immediate Follow-up Activities

Procedures for ARV drug management and respective forms agreed upon within the SOP working group will be integrated into the document by MSH, Ethiopia. MSH Arlington will assist as required. Further steps that will lead to the endorsement of the final document will be facilitated by MSH, Ethiopia.

Recommendations

The facility ARV drug quantification procedure is recommended to be reviewed by MSH staff and shall be made available to the health facilities.

At least in the initial stage of ART introduction MSH will have to actively oversee drug distribution by PHARMID. It is recommended for MSH to develop the electronic data base for drug management at ETAEP supported sites first as the information will be entered into the database at MSH office and can therefore be easier refined as necessary. The refined version could then be adapted for use at the MOH (PASS) and Regional Health Bureaus.

With the launch of ART implementation planned for January 2005, preparations for the second round of ARV drug procurement should follow suit shortly thereafter.

Important Upcoming Activities or Benchmarks in Program

The introduction of ART services is planned for January 2005.

Annex 1. Minutes of the First Review Meeting on the SOP for ARV Drugs Management in Health Facilities

Date: 29 October 2004
Venue: MSH Office

Introduction

The working group assigned to prepare SOP for ARV drugs management in health facilities developed the first draft of SOP at the end of a ten-days meeting at Nazareth in October 2004. Soon after the first draft of the SOP had been finalized, the copies were distributed to participating stakeholders from DACA, RPM Plus, PASS and KENEMA for review and comments before the document is distributed in its final form. Since this is the first experience in the country, incorporating different opinions and ideas from different stakeholders is believed to be essential to the success of the SOP in achieving its purpose. RPM Plus forwarded the document to MSH senior technical staff for review and comments.

One of the MSH staff, Hella Witt, reviewed the document and came up with various suggestions on the forms used and also proposed new forms and procedures to improve the management of ARV drugs and reporting procedures. These comments and suggestions were first thoroughly discussed with Hailu (RPM Plus Staff) who is a member of the SOP working group. The procedures and forms, which are identified to increase the efficiency of ARV drugs management, were suggested to be discussed with all members of the working group. As a result a review meeting was arranged for October 29, 2004.

RPM Plus also consulted pharmacy personnel at Zewditu Hospital to get their perspective on the practical applicability and feasibility of the suggested forms. The practicing pharmacy personnel at Zewditu Hospital commented that the forms (tools) are efficient and can be effectively used in managing ARV drugs. However, they were worried about the additional workload to complete the forms given the existing shortage of manpower. Thus they have quested for additional manpower at least to assist the recording of the information.

The meeting started at 9:00 A.M.

Participants

All members of the working group except one member from DACA were invited and participated in the meeting. RPM Plus also invited Shimels to participate in the meeting as he had long time experience in hospital pharmacy management.

Present were:

1. Hella Witt (MSH-RPM Plus)	Chair Person
2. Hailu Tadeg (MSH-RPM Plus)	Minute keeper and member of the SOP working group
3. Getahun Gurmessa (DACA)	Participant and member of the SOP working group
4. Sileshi Birhanu (PASS)	Participant and member of the SOP working group
5. Ayalew Adinew (KENEMA)	Participant and member of the SOP working group
6. Shimels Endailalu (MSH-RPM Plus)	Participant

PROCEEDINGS OF THE MEETING

The chairperson briefed participants on the purpose of the meeting and reviewed the outlines of the agenda. She also discussed the main procedures of how the meeting should proceed in addressing each issues included in the agenda. Then a consensus was reached as to how to go about through each points included to be discussed. The group assigned Hailu Tadeg to write the minutes and adapt the forms according to the agreements made. The minute was decided to be attached with the modified and new forms, that are agreed upon to be part of the SOP, and sent to the stakeholders for comments and review. All participants took the responsibility to discuss the SOP with their staff members and encourage all interested to read and forward their feedback. Finally the group decided all changes agreed upon by participants to be incorporated into the draft SOP by Hailu Tadeg.

1. Definition of Category of Institutions that Should use the SOP

Although there was a common understanding by the working group that the SOP will be used by all health facilities that are decided to run ART, this had not been properly stated in the draft SOP and hence creates confusion as to which health facilities are supposed to follow these procedures.

After having thorough discussion agreement was reached by all participants that the SOP shall serve to manage ARV drugs for all health facilities who receive free supply of ARV drugs.

2. Applicability of Some Transaction Procedures (e.g. the use of Models) to All Health Facilities

The draft SOP work group has developed different management forms for the management of ARV drugs. The use of Models in addition to the forms was also indicated in the SOP. Current experiences indicate that all public health facilities use Models as major transaction instruments for issuing and receiving drugs. However other organizations like Military and Police hospitals use their own forms or Models to carry out such transactions and hence the use of models to other categories of health facilities is questionable. Participants discussed the pros and cons of using and avoiding these models and agreed on the following points:

1. The forms developed for the management of ARV drugs will be the main management tools for inventory of ARV supplies.
2. In the public health facilities where using Models is a legal requirement, models should be used alongside with the management forms introduced in the SOP.
3. In non public health facilities, the transaction forms that are considered organizational requirements in that facility should be completed side by side with the management forms in the SOP and they should not necessarily use models.
4. In the SOP document the term Models should be restated as ***Models or equivalent forms***.

3. Review of Forms for Ordering and Receiving

a) Replacement of Requisition Form with Requisition and Approval Form

In the draft SOP, the working group had suggested the use of different forms for ordering drugs from the main store of the health facilities (Requisition and Approval Form) and from suppliers outside the health facilities (Requisition Form). In addition, Receiving and Inspection Reporting Form was suggested to be filled and sent to the supplier at all times receipts are made (whether there are discrepancies or not). This however is believed to increase the number of forms to be filled and disperses information into different forms, which might require additional work to compile these data.

Therefore the use of Requisition and Approval Form for making both internal and external transactions was proposed. This was suggested to have the following advantages:

1. Reduces the number of forms to be filled
2. Allows visualizing information about what has been ordered, supplied and received from the same form.
3. Makes MIS more accessible and efficient and avoids the necessity to write each items by the ordering, supplying and receiving sections as it can be preprinted and each section will fill only quantities.

Finally, participants agreed upon the use of Requisition and Approval Form for making both internal and external stock exchange. But the name of this form is suggested to be changed to ***Ordering and Receiving Form*** ***(See Annex A)*** so as to reflect its new

mission. A space for signature of a delivering person was suggested to be included in the supplying section of the ***Ordering and Receiving Form*** as receiving section could only be signed when drugs are inspected at the facility.

b) Use of Receiving and Inspection Reporting Form only in Cases of Discrepancies

The Receiving and Inspection Reporting Form was originally decided to be filled and sent to the supplier both as a feedback of receipts and as notice for replacement in cases of discrepancies. But filling additional forms at each time receipts are made will create work burden on the professionals and hence, this can be easily avoided by sending a copy of ***Ordering and Receiving Form*** to the supplier after filling the Items Received column (as feedback of receipts). But if discrepancies in the supplied and received quantities arise, Receiving and Inspection Reporting Form should be filled in and sent to the supplier for replacement. Since the form is therefore used to report discrepancies alone, its name is agreed to be changed to ***Discrepancy Reporting Form*** ***(See Annex B)***.

Another important issue in this regard that participants discussed was how to account for the discrepancies at the main store until they are replenished or disposed off. Because, once received and recorded into the stock card, this might give false figures about the usable stock. After having lots of debates participants agreed on the need to receive the discrepancies (such as expired or damaged items) through the formal procedures (i.e. Ordering and Receiving Form and Model 19 or equivalent forms) and record it into the stock cards notifying the quantities damaged or expired. Then all unusable stock should be transferred to a newly proposed form called ***Expiry and Damage Inventory Sheet*** ***(See Annex C)*** immediately after receipt. The unusable stock shall be stored separately from other items. All damaged or expired items are suggested to be recorded in this sheet until they are disposed off. The group assigned Hella and Hailu to design an ***Expiry and Damage Inventory Sheet*** ***(Annex C)*** form that could serve this purpose.

4. Review of Forms at the Dispensary

The major forms suggested in the draft SOP to be used at the dispensary were *ARV Drugs and Revenue Register* and *ARV Drugs and Patient Information Sheet*. The *Drugs and Revenue Register* was meant to monitor the money to be collected from patients according to the amount set in the eligibility criteria. However recent information indicates that this payment scale is lifted and all patients are expected to get medications free of charge irrespective of their income status. Therefore, the group agreed this form to be deleted from the SOP, as it will not have any practical relevance. The ***ARV Drugs and Patients Information Sheet*** ***(See Annex D)*** however is decided to be used with minor modifications.

A new form, the ***ARV Drugs Dispensing Register*** ***(See Annex E)*** was proposed to be used in the dispensary. After a thorough investigation of this form participants believed that this

form summarizes all the key informations required for reporting and MIS and hence improves the over all management of the ARV drugs and patients on ART. Therefore, participants unanimously supported the use of this form at the dispensary and its inclusion into the SOP.

Other points agreed upon by participants and suggested to be included in the SOP were:

1. Patients should get their medications from a single facility of their choice unless otherwise formally referred. This is to make the follow-up of patients easier and make more effective and efficient use of the ARV Drugs and Patient Information Sheet for the benefit of the patient.
2. Inpatient pharmacy should not supply ARV drugs for long term uses. Thus all patients should collect their monthly supply from the outpatient pharmacy where the ***ARV Drugs and Patient Information Sheet*** is kept. There may however be instances where patients are admitted to the hospital for any emergency treatment and could not bring their ARV drugs with them. For such cases the inpatient pharmacy should keep small amounts of emergency supplies. Recording of such informations at the inpatient pharmacy shall be made on the relevant forms to be prepared by Hella and Hailu.

   [See the suggested form under ***Annex F (ARV Drugs Dispensing Register For Post Exposure Prophylaxis)*****]**
3. PEP must be give as early as possible after the exposure. In order to provide access to PEP at all times, ARV drugs for PEP shall be kept at the pharmacy unit that provides 24 hours services. This will in most cases be the inpatient pharmacy.

   [See the suggested form under ***Annex G (ARV Drugs Dispensing for Emergency Supply)*****]**

5. MIS and M&E Requirements

a) The Management role of the pharmacist/pharmacy personnel in charge of ARV

The chairperson stressed the importance of empowering the pharmacist in charge to be able to manage the stock appropriately. The purpose of data collection and record keeping is firstly to allow the ARV pharmacist to have an overview of the trends in ART prescribing and developments in different HIV AIDS related activities like ART, PMTCT, PEP and OIs at the facility. Two new forms were presented to participants to discuss and comment on: ***ART Patients and Drug Use Overview (See Annex H) and ARV Drugs Consumption Overview (See Annex I).*** In these forms the number of patients and treatment characteristics as well as the drugs consumed are recorded every month from the ARV Drugs Dispensing Register. The overview allows to reasonably approximate the number of new patients expected to start ART in the next month and quantify drug requirements correctly. As there is no best formula for calculating future demands in such situations where no one can anticipate what the number look like in the coming month, securing such basic informations by the pharmacist, who also is in frequent communication with the prescribing clinicians, can be of significant

importance in forecasting the most reliable approximate quantities. Thus the group agreed on the inclusion of these forms in the SOP.

b) The Need to Measure Adherence

Adherence is one of the key issues to be addressed in ART. In the draft SOP, the issue of monitoring adherence was envisioned to be addressed in the individual ***ARV Drugs and Patient Information Sheet.*** This will make follow-up of adherence a bit tedious, as tracing non-adhering patients will be difficult unless each information sheet is investigated for non-compliance to appointment dates. This makes its applicability in monitoring adherence less practical. Thus a new adherence monitoring form was proposed. Participants discussed on its practical applicability and finally agreed on its inclusion in the SOP under the name called ***Patient Tracking Chart*** ***(See Annex J).***

According to this chart, a patient who fails to collect his/her medications on the last possible date will be labeled as either non-compliant, lost for follow-up or died. Participants tried to give operational definitions for these terms, as doing so was believed to be important to avoid confusions:

- A patient who failed to collect his/her medication on the last possible date is to be labeled as ***non-compliant***.
- A patient who fails to collect his/her medication for more than 1 month without known referral or announced treatment interruption/stopping of treatement is to be labeled as ***lost for follow-up***.
- A patient who has been reported to be passed away is to be labeled as ***died***.

c) Monthly Reporting Requirements

The monthly pharmacy activity report was suggested to be reorganized according to the new changes proposed and accepted by participants. Thus monthly reporting requirements were agreed upon to include ***Consumption and Stock Status*** ***(See Annex K)***, patient characteristics, use of other important drugs, ADR/side effects, reasons for switching regimes, etc, according to the new changes made on different forms. The monthly pharmacy activity reporting form was suggested to be reorganized and formatted by Hella and Hailu so as to include the new changes and also to make it more easier to fill and yet capable of offering relevant informations that can be easily analyzed and interpreted for decision making purposes. The outline of the most important information agreed upon to be included in the form is indicated under ***Annex L.***

d) Stock Exchange Between Health Facilities

Procedures for making exchanges of stocks between health facilities may sometimes be very important to minimize expiration of products and avoiding stock outs. But such activities if made without the knowledge of higher bodies like RHB, PHARMID, etc might have negative consequences in terms of following up stock status, re-supply, procurement and other decision making by the higher bodies. Thus participants agreed up on the need to inform higher bodies before making any stock exchange between health facilities. This information is also suggested to be clearly stated in the SOP.

6. Other Issues of Importance

a) Defining the Reporting Calendar

Participants discussed as to which calendar should best be used by the health facilities for reporting pharmacy monthly ART activities. Current experiences indicate that all public health facilities report in Ethiopian calendar. On the other hand KENEMA reports in both calendars i.e. in Ethiopian calendar to DACA and in international calendar to the head office. Reporting in both calendars will not only create an unnecessary additional work but also it might at times be confusing. Using either will have its own advantages and disadvantages. But, the group suggested the use of international calendars unless otherwise required by MOH and DACA because of the following reasons:

- Many of the informations about the drugs including the expiry dates are written in international calendars and hence will make follow-up of the medications easier.
- The electronic system that is expected to be installed at least in some facilities will easier to be configured with international calendar (e.g. to link it with the procurement and MIS system likely to be used by PASS and PHARMID) and hence the manual and electronic systems should coincide.
- Donor agencies need reporting in international calendars
- Reporting calendar for ART would not coincide with the date reported regularly to be made according to Ethiopian calendar.

b) Relevance of Including Delivery Note/Shipping Document in the SOP

In the draft SOP, Delivery Note/Shipping Document was included as one of the resources required in making receipts of supplies. It appears from the draft document that health facilities receive supplies directly from overseas, which actually is not the case. Since health facilities will not get directly involved in procurement and receipt of supplies from overseas, it is not necessary to mention this document in the SOP. Therefore participants agreed on its deletion from the SOP document.

c) Coding of Patients

Coding patients will be a necessity particularly for arranging the ***ARV Drugs and Patient Information Sheets*** according to some systems so as to easily locate a patient's information sheet. The best number available that is unique and could help to identify a specific patient and currently in place in health facilities is the card number. Therefore, it was agreed that the ***ARV Drugs and Patient Information Sheets*** be arranged by the order of the patient's card number. But, other codes that might be given by the facility (e.g. ART number, Appointment number, etc) which can uniquely identifies a patient may also be used as appropriate based on the existing system at each health facility.

d) Drug Codes/Abbreviations

The group suggested the use of the universally accepted abbreviations as codes for the drugs at the same time discouraged the use of more than one code name for a single

drug so as to avoid confusions that may arise as a result of doing so. For example, Zidovudine should be abbreviated as ZDV instead of AZT.

e) Brands and Stock Cards

The need to use different stock cards for different brands was questioned by some of the participants. But the experience in KENEMA indicates the importance of using different stock cards. It sounds logical at least theoretically that each brand should be accounted differently as the costs, country of origin, batch number and expiry dates might also differ. Participants agreed on the use of different cards for different brands and recommended for such information to be included in the SOP.

Finally, the presentation of the document, definition of the forms, short alternative name (abbreviations) for the forms and rewriting of the document according to the new changes were suggested to be worked out by Hailu in collaboration with Hella.

The meeting ended at 5:30 P.M.

Annex A. Ordering and Receiving Form

Ordering and Receiving Form

Name of Institution: _____

Ref. No.

Requesting Section:	Supplying Section:
Date Ordered:	Date Received:

Ser No	Items Ordered To be Filled out by Requester				Items Supplied To be Filled out by Supplier					Items Received To be Filled out by Receiver	
	Description (Name, strength, dosage form and pack size)	Unit	Stock on Hand	Quantity Ordered	Quantity Supplied	Expiry Date	Batch No	Unit Cost	Total Cost	Quantity Received	Remark/Discrepancy
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											
Ordered by:		Approved by:			Supplied by:					Received/inspected by:	
Signature:		Signature:			Signature:					Signature:	
Date:		Date:			Date:					Date:	
Delivery Mode:					Delivering person:				Signature:		
Comments:											

Annex B. Discrepancy Reporting Form

Invoice /AWB/Issue Voucher No.: _____
Reported by: _____ Reported to: _____
Date of inspection/Receipt/: _____

Ser No	Description of Items **(Name, Strength, Pack Size and dosage form)**	Unit	Batch No	Expiry date	Manufacturer or Country of origin	Quantity			Remark
						Expected	Actual Received	Discrepancy	

	Name	Signature	Date
Received By:	_____	_____	_____
Delivered By:	_____	_____	_____
Witnessed By:	_____	_____	_____

Annex C. Expiry and Damage Inventory Sheet

Name of the Health Institution: _____

Date	**Description of the Item** (Name, Strength, Pack Size and dosage form)	**Date Received**	**Receiving Voucher No (Model 19)**	**Received From**	**Unit**	**Qty.**	**Price**		**Reason for Transfer**			**Remark**	**Initial**
							Unit *Price*	Total Price	Expired	Damaged	Others		

Annex D. ARV Drugs and Patient Information Sheet

Patient Name: _____
Card No.: _____
Sex: _____
Age: _____
PMTCT Plus: ( ) yes ( ) No

Appointment Card No.: _____
Date ART Started: _____
ART Regimen on Start: _____
Prescription No: _____
Weight on Start: _____
Earlier TB treatment: ( ) yes ( ) No

Prescriber initiating treatment:
Name_____
Registration No.: _____
Qualification: _____
Working Place: _____
Tel.: _____

Date of Visit	Reasons for Visit (Start, Refill, Switch)	In patient or out patient	Prescriber		Wt. in Kg	Drug Code, Brand, Strength, Dosage form, Quantity	ADR & Side Effects	Reason for change	Other Drugs			Other Disease Conditions	Last Date of Next Visit	Sign
			Initial	Reg. No.					Prevention		Others			
									INH	Cotrimox.				

Annex E. ARV Drugs Dispensing Register

			Sex		Age Group							Reasons for Visit			Months of Supply Dispensed						First-line Adult Formulations										Pediatric Formulations						Second-line Drugs					Other Drugs			
Serial No	Date	Card No	Female	Male	Child <5 years	Child 5-17 years	Adult > 18	In-patients	PMTCT Plus	Weight above 60	Drugs Collected on time	Refill	Switch	Start	D4T/3TC/NVP	ZDV/3TC/NVP	D4T/3TC/EFV	ZDV/3TC/EFV	ZDV/ddI/LOPr	Other	For Combination?	For Combination?	D4T 30 mg	d4T 40mg	AZT 300mg	AZT+3TC 450 mg	3TC 150 mg	NVP 200mg	EFV 600mg	EFV 200mg	For EFV 50mg	For EFV 100mg	AZT 100mg	AZT 10mg/ml	3TC 10mg/ml	NVP 10mg/ml	For ABC or Tenofovir	ddI 25mg	ddI 100mg	LOP/r 113/33 mg	NFV 250mg	INH Prevention	Cotrimoxazole Prevention	TB treatment	Drugs for other OI's

Annex F. ARV Drugs Dispensing Register For Post Exposure Prophylaxis

This form is to be used at the inpatient pharmacy only for recording ARV drugs issued for the purpose of Post Exposure Prophylaxis.

Date	Profile of Exposed Individual					Source of Exposure			Prescribing Physician		Drugs Dispensed		Signature
	Name	**Age**	**Sex**	**Profession**	**Department**	**Needle Stick**	**Mucosa**	**Others**	**Initial**	**Reg. No**	**Description** (Name, Strength, Dosage form)	**Qty**	

Annex G. ARV Drugs Dispensing for Emergency Supply

This form is used for recording short-term supplies of ARV drugs that are dispensed to inpatients admitted to the hospital and who have forgotten to bring their regular ARV drugs.

Date	Patient Name	Card No	Drugs Dispensed		Prescribing Physician		Reasons for Supply	Signature
			Description (Name, Strength, Dosage form)	**Qty**	**Initial**	**Reg. No**		

Annex H. ART Patients and Drug Use Overview

Month	Total No of Patients Served	Sex		Age Group			No of Out-patients	No of In-patients	No of PMTCT Plus	Weight Above 60	Drugs Collected on Time	Reasons for Visit			Months of Supply Dispensed						No of Times a Regimen is Dispensed						Other Drugs Used				
		Female	Male	Child <5 years	Child 5-17 years	Adult > 18						Refill	Switch	Start	D4T/3TC/NVP	ZDV/3TC/NVP	D4T/3TC/EFV	ZDV/3TC/EFV	**ZDV/ddI/LOPr**	Other	D4T/3TC/NVP	ZDV/3TC/NVP	D4T/3TC/EFV	ZDV/3TC/EFV	**ZDV/ddI/LOPr**	Other	INH Prevention	Cotrimoxazole Prevention	Drugs for OI's	No of patients Died	Patients Lost to Follow-up

Annex I. ARV Drugs Consumption Overview

Month	No of patients		Quantities of First-line Adult Formulations Dispensed										Quantities of Pediatric Formulations Dispensed						Quantities of Second-line Drugs Dispensed				
	Total Patients	New Patients	For Combination?	For Combination?	D4T 30 mg	D4T 40mg	AZT 300mg	AZT+3TC 450 mg	3TC 150 mg	NVP 200mg	EFV 600mg	EFV 200mg	For EFV 50mg	For EFV 100mg	AZT 100mg	AZT 10mg/ml	3TC 10mg/ml	NVP 10mg/ml	For ABC or Tenofovir	ddI 25mg	ddI 100mg	LOP/r 113/33 mg	NFV 250mg

Annex J. Patient Tracking Chart

Health Facility: _____ **Year: _____**

Month: _____

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Remark

Month: _____

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Remark

Annex K. Consumption and Stock Status

ARV Drugs	Dosage Form	Unit	Pack Size	Quantity Consumed (Last Month)	Drugs used of PEP (Packs)	Drugs for Emergency Supply	Stock on Hand (Packs)	Drugs on Order (Pack)	Quantity Short Dated (<6 months)	No of Days Out of Stock (Last Month
Combination?										
D4T + 30 mg										
D4T 40mg										
AZT 300mg										
AZT+3TC 450 mg										
3TC 150 mg										
NVP 200mg										
EFV 600mg										
EFV 200mg										
For EFV 50mg										
For EFV 100mg										
AZT 100mg										
AZT 10mg/ml										
3TC 10mg/ml										
NVP 10mg/ml										
For ABC or Tenofovir										
ddl 25mg										
ddl 100mg										
LOP/r 113/33 mg										
NFV 250mg										

Annex L. Monthly ART Dispensing Report

Patient profile
Total # of patients
Female
Male
Child <5 years
Child 5-17 years
Adult > 18
Weight above 60 kg
%adults with weight over 60kg
Collected on time
% of refill collected on time:
Refill
Switch
Start
Out-patients:
In-patients:
PMTCT Plus:

Patients who stopped treatment
Patients died
Patients lost to follow-up

Treatment regimen used	**Number of months regimen is dispensed**
D4T/3TC/NVP	D4T/3TC/NVP
ZDV/3TC/NVP	ZDV/3TC/NVP
D4T/3TC/EFV	D4T/3TC/EFV
ZDV/3TC/EFV	ZDV/3TC/EFV
ZDV/ddI/LOPr	ZDV/ddI/LOPr
Other	Other

PEP patients in last month:
PMTCT services in last month:

Estimated # of new patients in next month
Your best estimate on new ART patients:
Child <5 years
Child 5-17 years
Adult > 18
Your best estimate of PEP patients:

 # ART patients receiving preventive treatment and OI drugs
INH Prevention
Primary Cotrimoxazole Prevention
Second. Cotrimoxazole Prevention
Drugs for OI's

Annex 2. Indicators for defining pharmacy preparedness to start ARV dispensing at health facilities

	yes	no	Remark
Infrastructure			
Secure space at bulk store available (lockable cabinet or lockable store room)			
Adequate space in lockable cabinet available at dispensaries			
Space for confidential patient counseling during dispensing available (booth, pharmacy office or other adequate room assigned for this purpose)			Describe:
Equipment and supplies			
Refrigerator with temperature control available at the out-patient pharmacy			
Sufficient cold storage space available at bulk store (fridge or cold room)			
Human resources			
At least one pharmacist, druggist, pharmacy technician trained in ART			
At least two pharmacy dispensers available that can be trained in ART			
M&E/MIS			
Stock record cards used			
SOP available for ARV management			
Monthly collection of ARV drugs feasible			
Stock status regularly recorded			
MOU regarding ARV drug management signed by facility			
Lockable filing cabinet or drawer suitable for ART documentation available (or respective space in storage cabinet)			